

CLAIMS

1. A method of optimizing cardiac resynchronization therapy provided to a patient with ventricular dysynchrony including the step of non-invasively measuring hemodynamic and pulmonary performance in terms of data indicative of a function selected from the group consisting of forward pump function (stroke volume output) or retrograde effects on filling pressures, pulmonary venous flow, and gas exchange at the alveolar/capillary membrane interface or a combination thereof.

5 2. A method as in claim 1 wherein said forward pump function of the heart is derived from the oxygen pulse (VO_2/HR).

10 3. A method as in claim 1 wherein said retrograde effect on filling pressures, pulmonary venous flow, and gas exchange at the alveolar/capillary membrane interface is derived from the ventilatory equivalent for CO_2 (VE/VCO_2).

15 4. A method as in claim 2 wherein said retrograde effect on filling pressures, pulmonary venous flow, and gas exchange at the alveolar/capillary membrane interface is derived from the ventilatory equivalent for CO_2 (VE/VCO_2).

5 5. A method as in claim 1 including the step of utilizing additional cardiopulmonary variables selected from the group consisting of end tidal CO_2 (ETCO_2) and the ventilatory efficiency slope (linear slope of VE/VCO_2).

20 6. A method as in claim 4 including the step of utilizing additional cardiopulmonary variables selected from the group consisting of end tidal CO_2 (ETCO_2) and the ventilatory efficiency slope (linear slope of VE/VCO_2).

25 7. A method as in claim 1 including the steps of displaying non-invasive, breath-by-breath cardiopulmonary variables and utilizing them to guide in the placement of a left ventricular lead to optimally achieve physical and electrical separation from a right ventricular lead.

8. A method as in claim 7 wherein said lead placement is performed outside of a sterile field during implantation surgery.

30 9. A method as in claim 6 including the step of acquiring and displaying said non-invasive cardiopulmonary exercise variables during low intensity exercise and storing them as data sets, each set being associated with a unique value of atrial-ventricular (AV)

delay and right ventricular-left ventricular (VV) delay.

10. A method as in claim 9 wherein the values for AV and VV delay are defined in a boundary conditions table unique to a pacemaker manufacturer of interest.

5 11. A method as in claim 9 including the step of utilizing the stored cardiopulmonary variable data sets to assist a physician in selecting the optimal combination of AV and VV delay values from several possible such values as defined in a boundary condition table unique to a pacemaker manufacturer of interest uniquely for individual patients.

10 12. A method as in claim 8 wherein selection of the optimal combination of AV and VV delay values includes the following steps:

- (a) executing an AV/VV Delay Optimization Protocol Execute defining a time schedule for System Operator Tasks and Data Processing Tasks for each unique value of AV and VV delay as defined in a boundary condition table unique to a pacemaker manufacturer of interest;
- (b) storing variable values measured for each breath during the Delay Optimization Protocol into a Stored Data Sets table for subsequent analysis;
- (c) computing and storing a central tendency and percent deviation from the central tendency for each measured variable in each data set obtained immediately after collection in step 9(b) into an Intermediate table for subsequent analysis;
- (d) computing and storing into a Decision Matrix ranking values for quantifying the response to changes in AV and VV delay settings using the values obtained in step 9(c);
- (e) computing and storing into a Decision Matrix deviation indices to provide a qualitative assessment of the variability of the data sets used to compute the ranking values obtained in step 9(d);
- (f) computing and storing into a Decision Matrix separation indices to provide a qualitative assessment of the magnitude of the difference between the central tendencies of the data sets used to calculate the ranking values

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- in step 9(d);
- (g) printing a report of the Decision Matrix with all values used to compute average rank, deviation, and separation in steps 9(d), 9(e), and 9(f);
- (h) printing a graphical report in the form of a histogram having two juxtaposed bars - one bar representing the ranking values determined in step (d), and another bar representing the average deviation % computed from step 9(e) - and the separation indices computed in 9(f); and
- (i) programming AV and VV delay values that provide the best forward pump function and the best retrograde effect on filling pressures, pulmonary venous flow, and gas exchange at an alveolar/capillary membrane interface using quantitative and qualitative data computed in steps (a) through (h).

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13. A method as in claim 12 wherein the variables computed in steps (a) to (f) are represented in other common graphical formats selected from the group consisting of lines, bars, and pie charts.

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14. A method wherein the variables are measured under steady-state conditions and are treated as dependent variables for the purposes of lead placement and selection of the optimal combination of AV and VV delay values which are independent variables.

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15. A method as in claim 1 wherein a common set of equipment is utilized to optimize all phases of cardiac resynchronization therapy, including device implantation and device programming.

16. A method as in claim 11 wherein a common set of equipment is utilized to optimize all phases of cardiac resynchronization therapy, including device implantation and device programming.

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17. A method as in claim 11 wherein decisions can be made from quantitative and qualitative information.

18. A method as in claim 1 including the step of measuring retrograde effects using an end-tidal CO₂ analyzer.